

**REMARKS**

Claims 1, 2, 4-17, 19-23 and 56-73 are pending in the application and are currently rejected. Claims 4, 5, 15, 61, 68, and 73 have been amended, and claim 9 has been canceled. In light of the amendments and remarks herein, reconsideration of claims 1, 2, 4-8, 10-17, 19-23 and 56-73 is respectfully requested.

**Amendments to the Claims**

While Applicants believe that the previously presented claims are patentable over all of the art cited in the Office Action as well as all other references submitted by Applicants, the claims have nonetheless been amended as follows in order to expedite the application toward allowance. The amendments are therefore made without prejudice or disclaimer, and Applicants reserve the right to pursue the original scope of the claims as provided prior to the cancellation or amendments, such as through continuation practice.

Claim 4 is amended to address the Examiner's objection to the claim.

Claim 5 is amended to provide clarifying language for the claim.

Claim 9 is cancelled to address the Examiner's double patenting rejection.

Claim 15 is amended to recite a handle adapted to conduct heat, and a heat sink thermally coupled to said at least one radiation source and said handle and configured to conduct heat from said at least one radiation source to said handle during operation of said at least one radiation source. Support for the amendments is found in FIG. 1 (see elements 20 and 22), and in the detailed description at paragraphs [0094] and [0102] of the published application.

Claim 61 is amended recite an applicator having at least one protuberance and to recite "a total internal reflection mechanism coupled to said skin-contacting surface to prevent at least a portion of the radiation from passing through said skin-contacting surface unless in contact with a surface having an index of refraction approximately greater than or equal to the index of refraction of the skin contacting surface." Support for this amendment is found in FIGS. 5A-5D

and in the disclosure at paragraphs [0088] and [0104]. Support for the amendment can also be found throughout the pending claims of the application (e.g., claim 1).

Claim 68 is amended to recite an applicator having at least one protuberance. Support for the amendment is found throughout the pending claims of the application (e.g., claim 1).

Claim 73 is amended to recite a heat sink configured to remove heat from said at least one radiation source to an operator's hand. Support for the amendments is found in FIG. 1 (see elements 20 and 22), and in the detailed description at paragraphs [0094] and [0102] of the published application.

As such, the amendments to claims 4, 5, 15, 61, 68, and 73 do not add any new matter.

### **Novelty**

Claims 15 and 73 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,300,097 to Lerner et al. (herein "Lerner"). Both claims are novel, however, because Lerner fails to teach or suggest the elements recited in the amended claims.

Amended claim 15 recites an apparatus for treating skin comprising an applicator, an optical radiation source coupled to said applicator, a handle capable of "conducting heat," and "a heat conducting element thermally coupled to said at least one radiation source and said handle and configured to conduct heat from said at least one radiation source to said handle during operation of said at least one radiation source." In contrast, Lerner is directed to a fiber optic psoriasis treatment device for applying high energy UV radiation that does not disclose (i) a handle that would "conduct heat," or (ii) "a heat sink thermally coupled to said at least one radiation source and said handle." Lerner is silent as to the existence of a heat sink, and, even if a heat sink were disclosed, Lerner discloses a handle that is made of insulating material and that essentially would not conduct heat.

As depicted in FIGS. 1 and 2 of Lerner, and also as described in the associated disclosure, the body member 22, which includes the handle 26, is preferably "formed of a molded resinous material, such as plastic, rubber, and the like." (See Lerner, column 3, lines 62-

65). No other materials are mentioned. However, rubber is commonly known to be an insulator. (See, e.g., U.S. Patent 3,061,667, Col. 3:34-43 (disclosing telegraph pole line insulator made of rubber).) Similarly, as shown in attached Exhibit A (excerpt from Rodriguez, Principles of Polymer Systems, 2<sup>nd</sup> edition, McGraw Hill, New York, 1982, p. 266) the thermal conductivity of most polymers is around  $4.1 \times 10^{-4} \text{ cal sec}^{-1} \text{ cm}^{-1} \text{ K}^{-1}$  (this is equivalent to about  $0.1 \text{ Btu/ft}^{-1} \text{ hr}^{-1} \text{ F}^{-1}$ , which is midpoint of the range of thermal conductivity values cited by Rodriguez). In comparison, aluminum, which is named as an exemplary heat sink material in the application (see paragraph [0094] of the published application), is *approximately one-thousand times more thermally conductive* than a typical polymer (i.e., about  $5 \times 10^{-1} \text{ cal sec}^{-1} \text{ cm}^{-1} \text{ K}^{-1}$  as shown in Exhibit B, excerpted from Bird, Stewart, Lightfoot, Transport Phenomena, John Wiley & Sons, Inc., New York, 1960, p. 249).

The device in Lerner does not inherently draw heat away from the source into the head and the handle, as stated in the Office Action at page 3. To the contrary, assuming, *arguendo*, a socket for mounting were inherent and that the socket further inherently had the ability to draw heat from the source to the head and handle, the drawing of heat would not occur as suggested, because the head and handle as disclosed are made of materials, such as rubber and plastic, that typically do not conduct heat. Furthermore, Lerner may have taught the use of insulating materials to avoid overheating of the handle by the UV source and damage to the operator's hand, and, therefore, it cannot be presumed that a heat sink or conduction of heat in the handle is inherent in Lerner. Regardless, the explicit disclosure in Lerner does not disclose, and teaches away from, the claimed subject matter of amended claim 15 by teaching the use of insulating materials in the body and handle.

Similarly, amended claim 73 is also novel over Lerner. As discussed above, Lerner does not disclose, and teaches away from, "a heat sink configured to remove heat from said at least one radiation source to an operator's hand" as recited in amended claim 73. Lerner discloses a handle composed of materials that typically do not conduct heat to a significant degree and that are generally considered insulators, such as rubber and plastic. These materials likely would obstruct the transfer of heat from the handle to an operator's hand. Furthermore, Lerner does not disclose the use of a heat sink of any kind.

Accordingly amended claims 15 and 73 are novel and patentable over Lerner.

**Nonobviousness**

*Claims 1, 2, 4-14, 19-21 and 56-72*

Claims 1, 2, 4-14, 19-21 and 56-72 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Lerner in view of U.S. Patent No. 6,273,884 to Altshuler et al. (herein “Altshuler”). The claims, however, are patentable because there is no suggestion or motivation to modify the psoriasis treatment device of Lerner with the total internal reflection lens of Altshuler.

Claim 1 is directed to an apparatus for treating the skin, comprising an applicator having at least one protuberance comprising a skin-contacting surface, and at least one optical radiation source. The apparatus also includes a total internal reflection mechanism *to prevent a portion of the radiation from passing through said skin-contacting surface unless in contact with the skin.*

Lerner, the primary reference, is directed to a fiber optic psoriasis treatment device for applying UV radiation. Lerner does not disclose or suggest a total internal reflection mechanism that prevents a portion of the radiation from passing through said skin-contacting surface, unless in contact with the skin. Rather, Lerner teaches away from such a mechanism by relying on an opposite principle of operation. Lerner instead provides features and discloses a procedure in which UV radiation is transmitted even when not in contact with the skin. As shown in FIGS. 1, 2, 3A, and 3B, the distal tips of the fibers fixed to the body member of the apparatus have either UV radiation transmitting spherical elements or rounded ends, both of which have “a radius of curvature of about 0.25-2.0 mm, to ensure that minimal damage is done to the skin during use.” (see Lerner, column 4, lines 25-31). Lerner, therefore, teaches a device that is *configured to facilitate UV radiation transmission even when not in contact with the skin* to achieve a purpose other than energy conservation and safety measures as taught by the Applicants. Furthermore, Lerner discloses a procedure for controlling the dose of radiation that requires UV radiation to pass even when the ends are not in contact with the skin. Specifically, Lerner’s device “might

require the user to *point the output onto a detector* which measured irradiance appropriately” (see *id.* at column 5, lines 65-68).

As discussed in the Manual of Patent Examining Procedure §2143.02 Section VI, “[i]f the proposed modification or combination of prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious.” Adding the total internal reflection mechanism recited in amended claim 1 would change of the principle of operation of the tip ends of the fibers of the Lerner device and the suggested manner of calibrating the device. Accordingly, Lerner cannot be combined with Altshuler to render amended claim 1 obvious.

Claims 2, 4-8, 11-14, 19-21, and 56-60 all depend from claim 1, and are thus patentable over the cited art for at least the same reasons that claim 1 is patentable. In addition, the claims are patentable for other reasons.

In claims 6-7, the Applicants claim a range of power densities that extend significantly higher, by several orders of magnitude, than those disclosed by Lerner. Further, Applicants’ disclose using a broader range of energy, that is not limited to UV radiation as in Lerner. As the examiner notes, Lerner discloses power densities that are preferably 1-10 mW/cm<sup>2</sup> for UV-B radiation and 30- 1000 mW/cm<sup>2</sup> for UV-A radiation. In contrast, the Applicants, in Claim 6, claim a range of “between approximately 1 mW/cm<sup>2</sup> and approximately 100 W/cm<sup>2</sup>, the radiation depending at least on the condition being treated and the wavelength of the radiation.” Similarly, claim 7 recites a range of power densities of “between 10 mW/cm<sup>2</sup> and 10 W/cm<sup>2</sup>.”

Claim 10 is directed to a skin treatment apparatus that includes “a skin contacting end of each protuberance [having] total internal reflection for [] radiation when not in contact with the skin, but passes radiation to the skin when in contact therewith.” Accordingly, claim 10 is not obvious in light of Lerner and Altshuler since Lerner teaches away from utilizing distal fiber ends to confine radiation when not in contact with the skin, as discussed above.

Regarding claims 59 and 60, Lerner does not teach or suggest the arrays of optical sources as claimed by Applicants, and there is no motivation to combine those claimed features

with Lerner. Lerner discloses and claims only embodiments having only a single UV source. (See e.g. Cols. 4:5-10; 4:63-5:6 and claims 1 and 3-8. Further, Lerner discloses embodiments using single fluorescent bulbs, lamps (such as tungsten halogen lamps or mercury lamps), or an excise laser. (See Lerner Cols. 2:40-49; 4:5-10; 4:63-5:6.)) Lerner does not teach or suggest an array of optical sources, including an array of diode sources or an array of other types of sources, and there is no evident motivation to combine the references.

Claim 61 is directed to a skin treatment apparatus that includes a total internal reflection mechanism coupled to said skin-contacting surface to prevent at least a portion of the radiation from passing through said skin-contacting surface unless in contact with a surface having an index of refraction approximately greater than or equal to the index of refraction of the skin contacting surface. As such, claim 61 is not obvious in light of Lerner and Altshuler for substantially the same reasons that claim 1 is not obvious. Accordingly, claims 62-67, dependent from claim 61, are also not obvious.

Claim 68 is directed to a skin treatment apparatus having an optical radiation source that delivers optical radiation such that at least a portion of the radiation passes to the skin only when the surface contacts the skin. Accordingly, claim 68 also is not obvious in light of Lerner and Altshuler for substantially the same reasons that claim 1 is not obvious. Accordingly, claims 69-72, dependent from claim 61, are also not obvious.

#### *Claim 16*

Claim 16 is rejected under 35 U.S.C. §103(a) as being unpatentable over Lerner in view of Altshuler and further in view of U.S. Patent No. 6,572,637 to Yamazaki et al. (herein "Yamazaki"). Claim 16, dependent from claim 1, is patentable for essentially the same reasons that claim 1 is patentable. In particular, like Lerner and Altshuler, Yamazaki fails to provide the necessary suggestion or motivation to combine the references to include a total internal reflection mechanism. Yamazaki is silent in that regard.

*Claim 17*

Claim 17 is rejected under 35 U.S.C. §103(a) as being unpatentable over Lerner in view of Altshuler and further in view of U.S. Patent No. 5,445,608 to Chen et al. (herein “Chen”). Claim 17, dependent from claim 1, is patentable for essentially the same reasons that claim 1 is patentable. In particular, like Lerner and Altshuler, Chen fails to provide the necessary suggestion or motivation to combine the references to include a total internal reflection mechanism.

Further, the references effectively teach away from their combination. The procedures and devices disclosed in Chen are substantially different in kind from those disclosed in Lerner. Lerner concerns a surface skin treatment brush for inflammatory dermatoses, while Chen concerns an invasive *in vivo* procedure using a catheter, in which a photoreactive agent is administered through the catheter to inject it into the treatment site. (Compare Lerner Col. 2:34-39 and Chen Col. 4:7-15.) Further, Lerner teaches a procedure in which a “medicant or lubricant” is preferably applied to a surface region to be treated during a “pre-treatment” step, (see Lerner Col. 3 10-25), while Chen discloses a injecting the “photoreactive agent” to perfuse the treatment site *in vivo* after the catheter in Chen device has been inserted into the tissue, (see Chen Col. 4:7-15). There is no evident motivation to include the fluid delivery system of a catheter system with Lerner’s device for treating tissue at the surface. The two devices are so different that it would not be obvious to combine them.

*Claims 22 and 23*

Claims 22 and 23 are rejected under 35 U.S.C. §103(a) as being unpatentable over Lerner in view of Altshuler and further in view of U.S. Patent No. 6,350,276 to Knowlton (herein “Knowlton”). The claims are patentable, however, because none of the references teach the element of “a heat sink component in thermal contact with said at least one source, said component being adapted to be cooled prior to use of the apparatus” as recited in amended claim 22.

As discussed earlier, Lerner does not disclose a heat sink structure, and does not disclose a need for the cooling system of Knowlton. Lerner does not disclose either removing heat from the device itself or cooling the skin to prevent thermal damage, and there is no disclosure in Lerner that the device operates at a level of power that would require either a heat sink or skin cooling. Thus, there is no expressed motivation to combine the devices of Lerner, Altshuler and Knowlton.

Furthermore, Knowlton discloses a skin modification surface that includes a fluid delivery device that is structurally distinct from the claimed invention and that would require substantial modification even if combined. As shown in FIG. 2B by structure 13' and as recited in Knowlton, the cooling device "serves to deliver fluid to tissue interface 21 and surrounding tissue to prevent or otherwise *reduce thermal damage of the skin surface with the topical application of energy*" (see Knowlton, column 4, lines 57-61 (emphasis added)). Claim 22 recites a heat sink in thermal contact with the source that may be pre-cooled prior to operation of the device. The claimed device is too different structurally to be obvious in light of Knowlton.

Claim 23 is dependent from claim 22, and is accordingly patentable for at least the same reasons that claim 22 is patentable.



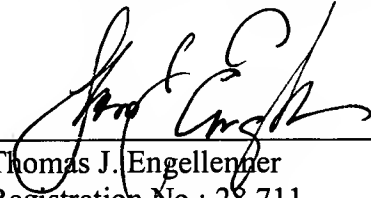
### CONCLUSION

In summary, the above-identified patent application has been amended and reconsideration is respectfully requested for all the reasons set forth above. In the event that the amendments and remarks are not deemed to overcome the grounds for rejection, the Examiner is kindly requested to telephone the undersigned representative to discuss any remaining issues.

Respectfully submitted,

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